DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

1065

January 18, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 26

Peter M. Bartling
Executive Director
Consulting Radiologists, Ltd.
1500 Medical Arts Building
825 Nicollet Mall
Minneapolis, Minnesota 55402

Dear Mr. Bartling:

On December 13, 2000, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your Consulting Radiologists, Ltd. facility at 6545 France Ave. So., Southdale Medical Center, Suite 302, Edina, MN 55435 (FDA certificate no. 158048). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

1. Radiologic technologist [redacted] did not meet the requirement of being licensed by a State or certified by a FDA-recognized board. Documentation supplied during the inspection indicated that her certification had expired.

Level 2 Non-Compliances:

2. Interpreting physician [redacted] did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6-month period).

3. Interpreting physician [redacted] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.

   An Attestation Form was left at the site for [redacted] to sign. As of January 16, 2001, neither attestation nor alternative documentation regarding items 2 and 3 has been supplied.

4. Interpreting physician [redacted] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.

   Since her training appears to have been completed after October 1, 1994, an attestation for this requirement is unacceptable. Acceptable documentation would be a letter from her residency program or copies of CME certificates.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

All individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. Conditions for "Direct Supervision" of unqualified personnel are specified in regulation and formal FDA policy. Policy references may be found at the Internet address below.

For a technologist, "Direct Supervision" means that the qualified supervising technologist is present to observe and correct, as needed, the performance of the trainee. <u>This requires that the qualified technologist be in the examination room itself during the time the examination is being conducted.</u>

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

James A. Rahto
Director
Minneapolis District

TWG/ccl

xc:

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